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ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

February 28, 2017

Dr. Anne Schuchat
Acting Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329

Dear Dr. Schuchat:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee continues to examine the Centers for Disease Control and Prevention's (CDC) Laboratory Response Network (LRN), a national network of local, state, and federal public health, food testing, veterinary diagnostic, and environmental testing laboratories that provide the laboratory infrastructure and capacity to respond to biological and chemical terrorism, and other public health emergencies. The more than 150 laboratories that make up the LRN are affiliated with federal agencies, military installations, international partners, and state/local public health departments.

Protecting the nation against a potential bioterrorism event is a high priority. To support this effort, the CDC LRN was established and became operational in 1999. The goal of the CDC LRN was to ensure that the nation has appropriate coverage and rapid detection technology and assays to quickly test suspicious materials and detect potential events suspected to be a result of bioterrorism in a timely manner to initiate immediate clinical intervention, surveillance, initiation of post-exposure prophylaxis, and other public health measures such as quarantine to save lives. Following the enactment of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, a specific goal of the LRN was to develop, maintain, and strengthen the capacity of LRN laboratories to address public health threats from federal select agents.

On August 11, 2016, the Committee sent a letter to the Director for the CDC, Dr. Thomas Frieden, seeking information about the current capabilities of the CDC LRN. On October 26, 2016, the Committee sent follow-up questions to the CDC's September 10, 2016 response to obtain further details on the CDC LRN.

We are in receipt of Dr. Frieden's December 22, 2016 response to our October 26, 2016 letter requesting additional information about the bioterrorism preparedness capabilities of the CDC LRN.

We appreciate the CDC's efforts put forth in the December 22, 2016 letter, and the detailed information provided. The Committee requests additional clarity on the assays the LRN has developed and deployed for all federal select agents, and requests the CDC's cooperation in providing the information in the format specified by the Committee. We also have additional questions and seek additional information raised by the CDC's previous responses.

To assist the Committee, please provide the following by March 14, 2017:

1. A table delineating the following information: name of each federal select agent, tests developed for detecting each federal select agent, names of LRN labs that have each test, dates of when these tests were deployed to the LRN labs, and for each test indicate whether the test was evaluated and validated by the CDC as described in the December 22, 2016 letter.

2. For each of the last fifteen fiscal years, provide the level of funding from the budget of the CDC Division of Preparedness and Emerging Infections that was allocated to support the LRN.

    (a) For each of the last fifteen fiscal years, how much was spent to maintain LRN re-agents?
    (b) For each of the last fifteen fiscal years, how much was spent on research and development efforts on assays for the LRN?
    (c) For each of the last fifteen fiscal years, how much was spent on the hiring of staff to support the LRN activities, and how many staff were hired to support LRN activities? Of the additional staff hired, how many worked full-time to support LRN activities? How many worked part-time to support LRN activities?

3. For each of the last fifteen fiscal years, how much funding has been provided to CDC by the Department of Homeland Security and any other federal agencies to support LRN activities?

4. Please provide a list of assays developed for the LRN by the CDC that have been submitted to the FDA for 510(k) clearance, the dates of submission, and the status.

5. CDC's December 22, 2016 letter stated, "As good stewards of limited government resources, CDC prioritizes tests based on their ability to have the greatest potential impact." Which tests is CDC referring to? How does CDC make such a determination? What are the criteria? Please provide any documents in support of this statement.

6. CDC's December 22, 2016 letter stated, "The LRN RT-PCR assays are less sensitive than culture when viable organisms are in the sample and a reliable culture-based assay is available." Please provide any data and documents in support of this statement.

7. CDC's December 22, 2016 letter stated, "The LRN routinely uses RT-PCR and culture on samples in order to obtain the most rapid identification of an organism, evaluate the organism's viability, and if viable, assess the organism's antimicrobial sensitivity." Please provide any data and documents in support of this statement.

8. With regard to CDC's development of a rapid, highly sensitive assay that can be performed on a commercially available, MALDI-TOF mass spectrometry platform, CDC's December 22, 2016 letter stated that this assay "is entering the third of six phases of development" of the Laboratory Assay Development and Design Control Review Process Operating Procedure before submission to the FDA for 510(k) clearance and deployment into the LRN. Please provide the details about each of the six phases. Have all assays developed by CDC for the LRN undergone the six-phase process? If not, why not?

9. CDC's December 22, 2016 letter stated that the CDC established the Assay Development Working Group in 2016. Please provide the names of the members and their agencies. Has the Working Group met? If so, when? What was the outcome of the meeting(s)?

Thank you for your prompt attention to this request. An attachment to this letter provides additional information about responding to the Committee's request. Please contact Alan Slobodin with the Committee staff at (202) 225-2927 with any questions about this request.

Sincerely,

Greg Walden
Chairman
Committee on Energy and Commerce

Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Frank Pallone, Jr., Ranking Member
Committee on Energy and Commerce

The Honorable Diana DeGette, Ranking Member
Subcommittee on Oversight and Investigations

Attachment